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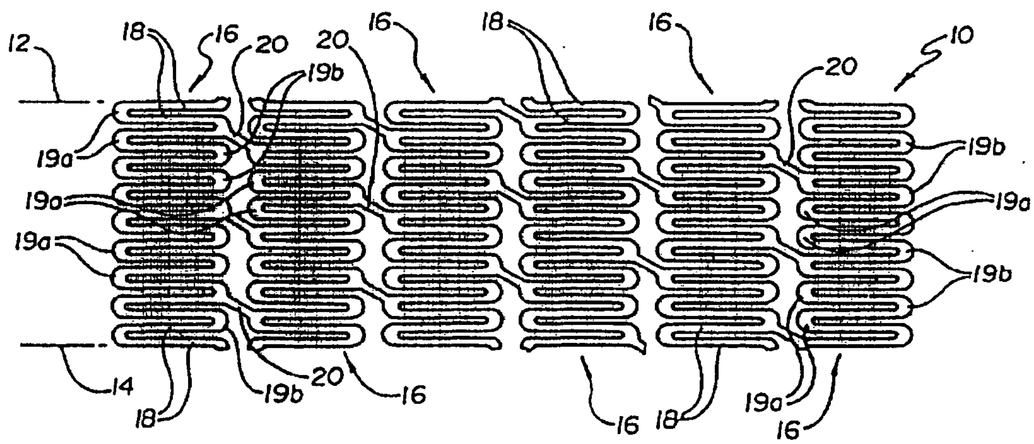
(54) **Improved longitudinally flexible expandable stent**

(57) Segmented articulatable stent of open structure comprised of end-connected struts making up the segments with angular interconnects between segments.

Fig. 1



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VV. USSN. 10/132,754

Description

[0001] This application is a Continuation of application Serial No. 08/396,569, filed March 1, 1995, the disclosure of which is hereby incorporated by reference.

Field of the Invention

[0002] This invention relates to an endoprosthesis device for implantation within a body vessel, typically a blood vessel. More specifically, it relates to a tubular expandable stent of improved longitudinal flexibility.

Background of the Invention

[0003] Stents are placed or implanted within a blood vessel for treating stenoses, strictures or aneurysms therein. They are implanted to reinforce collapsing, partially occluded, weakened, or dilated sections of a blood vessel. They have also been implanted in the urinary tract and in bile ducts.

[0004] Typically, a stent will have an unexpanded (closed) diameter for placement and an expanded (opened) diameter after placement in the vessel or the duct. Some stents are self-expanding and some are expanded mechanically with radial outward force from within the stent, as by inflation of a balloon.

[0005] An example of the latter type is shown in U.S. Patent No. 4,733,665 to Palmaz, which issued March 29, 1988, and discloses a number of stent configurations for implantation with the aid of a catheter. The catheter includes an arrangement wherein a balloon inside the stent is inflated to expand the stent by plastically deforming it, after positioning it within a blood vessel.

[0006] A type of self-expanding stent is described in U.S. Patent No. 4,503,569 to Dotter which issued March 12, 1985, and discloses a shape memory stent which expands to an implanted configuration with a change in temperature. Other types of self-expanding stents not made of shape memory material are also known.

[0007] This invention is directed to stents of all these types when configured so as to be longitudinally flexible as described in detail hereinbelow. Flexibility is a desirable feature in a stent so as to conform to bends in a vessel. Such stents are known in the prior art. Examples are shown in U.S. Patent No. 4,856,516 to Hillstead; U. S. Patent No. 5,104,404 to Wolff; U.S. Patent No. 4,994,071 to MacGregor; U.S. Patent No. 5,102,417 to Palmaz; U.S. Patent No. 5,195,984 to Schatz; U.S. Patent No. 5,135,536 to Hillstead; U.S. Patent 5,354,309 to Shepp-Pesch et al.; EPO Patent Application 0 540 290 A2 to Lau; EPO Patent Application No. 0 364 787 B1 to Schatz, and PCT Application WO 94/17754 (also identified as German Patent Application 43 03 181).

[0008] Generally speaking, these kinds of stents are articulated and are usually formed of a plurality of aligned, expandable, relatively inflexible, circular segments which are interconnected by flexible elements to form a generally tubular body which is capable of a degree of articulation or bending. Unfortunately, a problem with such stents is that binding, overlapping or interference can occur between adjacent segments on the inside of a bend due to the segments moving toward each other and into contact or on the outside of a bend the segments can move away from each other, leaving large gaps. This can lead to improper vessel support, vessel trauma, flow disturbance, kinking, balloon burst during expansion, and difficult recross for devices to be installed through already implanted devices and to unsupported regions of vessel.

[0009] A diamond configuration with diagonal connections between each and every diamond of each segment is also known but such closed configurations lack flexibility.

[0010] It is an object of this invention to provide a longitudinally flexible stent of open configuration that avoids these problems and exhibits improved flexibility (radially and longitudinally) in the stent body segments thereof rather than in flexible joints between the segments.

Summary of the Invention

[0011] To this end, the invention provides a tubular expandable stent, comprising: a plurality of cylindrical shaped open cylindrical segments aligned on a common longitudinal axis to define a generally tubular stent body, each segment being defined by a member formed in an undulating flexible pattern of interconnected substantially parallel struts with pairs thereof having alternating interconnecting end portions to define the periphery of the expandable stent segment, and in which the connected end portions of paired struts in each segment, before the stent is expanded, are positioned substantially opposite to connected end portions of paired struts in adjacent segments. The segments are interconnected by a plurality of interconnecting elements extending from some of the connected end portions on one segment to some of the connected end portions on adjacent segments in such a manner that there are three or more legs between points of connection from one side of each segment to its other side. Additionally, the connecting elements extend angularly from connecting end portion of one segment to connecting end portion of an adjacent segment, not to an opposite connecting end portion on an adjacent segment, whereby upon expansion of the stent the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate flexing of the stent within paired struts without interference between adjacent segments, rather than by means of articulating flexible connectors between segments. As a result, the connectors between the segments are not intended to flex or bend under normal use.

Brief Description of the Figures

[0012]

Figure 1 shows a flat view of an unexpanded stent configuration according to the invention.
Figure 2 shows the pattern of Figure 1 in a tubular, unexpanded stent.
Figure 3 shows an expanded stent of the configuration shown in Figure 1.
Figure 4 shows a flat view of an alternate unexpanded stent configuration according to the invention.

Best Mode Description of the Invention

[0013] Turning to the Figures, Figure 1 and Figure 2 show a fragmentary flat view of an unexpanded stent configuration and the actual tubular stent (unexpanded), respectively. That is, the stent is shown for clarity in Figure 1 in the flat and may be made from a flat pattern 10 (Figure 1) which is formed into a tubular shape by rolling the pattern so as to bring edges 12 and 14 together (Figure 1). The edges may then joined as by welding or the like to provide a configuration such as that shown in Figure 2.

[0014] The configuration can be seen in these Figures to be made up of a plurality of adjacent segments generally indicated at 16, each of which is formed in an undulating flexible pattern of substantially parallel struts 18. Pairs of struts are interconnected at alternating end portions 19a and 19b. As is seen in Figure 1, the interconnecting end portions 19b of one segment are positioned opposite interconnecting end portions 19a of adjacent segments. The end portions as shown are generally elliptical but may be rounded or square or pointed or the like. Any configuration of end portions is acceptable so long as it provides an undulating pattern, as shown. When the flat form 10 is formed into an unexpanded tube as shown in Figure 2, the segments are cylindrical but the end portions 19 of adjacent segments remain in an opposed position relative to each other.

[0015] A more preferred method of manufacture begins with a thin walled tube which is then laser cut to provide the desired configuration. It may also be chemically etched or EDM'd (electrical discharge machined) to form an appropriate configuration.

[0016] Interconnecting elements 20 extend from one end portion 19 of one segment 16 to another end portion 19 of another adjacent segment 16 but not to an oppositely positioned end portion 19 of an adjacent segment 16. There are at least three struts included between the points on each side of a segment 16 at which an interconnecting element 20 contacts an end portion 19. This results in the interconnecting elements 20 extending in an angular direction between segments around the periphery of the tubular stent. Interconnecting elements 20 are preferably of the same length but may vary from one segment to the other. Also, the diagonal direction may reverse from one segment to another extending upwardly in one case and downwardly in another, although all connecting elements between any pair of segments are substantially parallel. Figure 1, for example shows them extending downwardly, right to left. Upwardly would extend up left to right in this configuration.

[0017] As a result of this angular extension of the interconnecting elements 20 between adjacent segments and loops, upon expansion of the stent as seen in Figure 3, the closest adjacent end portions 19 between segments 16 are displaced from each other and are no longer opposite each other so as to minimize the possibility of binding or overlapping between segments, i.e., pinching.

[0018] The number of interconnecting elements 20 may vary depending on circumstances in any particular instance. Three per segment are satisfactory for the configuration shown and at least three will be used typically.

[0019] The alternate design shown in Figure 4 includes longer struts 18a in the two end segments 16a than in the intermediate segments 16. This allows the end segments (16a) to have less compression resistance than the intermediate segments (16), providing a more gradual transition from the native vessel to the support structure of the stent. Otherwise, the configuration is the same as that shown in Figure 1.

[0020] As already indicated, this invention is applicable to self-expanding configurations, mechanically expandable configurations and to a wide variety of materials, including both metal and plastic and any other material capable of functioning as an expandable stent. For example, the stent may be of metal wire or ribbon such as tantalum, stainless steel or the like. It may be thin-walled. It may be of shape memory alloy such as Nitinol or the like, etc.

[0021] The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

Claims

1. A stent, comprising:

a plurality of cylindrical segments including end segments and intermediate segments, the intermediate segments disposed between the end segments, each cylindrical segment formed of an undulating pattern of struts;
cylindrical segments which are adjacent one

another connected by a plurality of interconnecting elements, the interconnecting elements extending angularly from an end of one of the adjacent cylindrical segments to an end of the other of the adjacent cylindrical segments,
the distribution of interconnecting elements being such that for each intermediate segment, there are at least three struts separating interconnecting elements extending from one end of the intermediate segment and interconnecting elements extending from another end of the segment,
the interconnecting elements shorter in length than the cylindrical segments;
except where the stent is a tubular, flexible, expandable stent having a longitudinal axis and comprises the following feature combination:

(a) a plurality of cylindrical shaped segments aligned on a common longitudinal axis to define a generally tubular stent body,
(b) each segment being defined by a member formed in an undulating pattern of interconnected substantially parallel struts to define the periphery of the expandable stent body,
(c) and in which adjacent struts in a given segment are alternately interconnected at opposite ends,
(d) the interconnected ends of struts of one segment being positioned substantially opposite to interconnected ends of an adjacent segment, and
(e) a plurality of interconnecting elements each extending angularly from one end on one segment to another end, not to an opposite end, on an adjacent segment,
(f) the distribution of the interconnecting elements being such that there are at least three struts between each connecting point on opposite sides of the segments, and
(g) the interconnecting elements are not flexing or bending under normal use,
(h) whereby upon expansion of the stent the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

2. The stent according to claim 1, wherein the stent has a tubular, flexible, expandable body.

3. The stent according to any one of claims 1 or 2, wherein the stent has a longitudinal axis.

4. The stent according to any one of claims 1 to 3, wherein the cylindrical segments are aligned on a common longitudinal axis to define a generally tubular stent body.

5. The stent according to any one of claims 1 to 4, wherein adjacent struts in a given segment are alternately interconnected at opposite ends.

6. The stent according to any one of claims 1 to 5, wherein the interconnected ends of struts of one segment are positioned substantially opposite to interconnected ends of an adjacent segment.

7. The stent according to any one of claims 1 to 6, whereby upon expansion of the stent the paired struts of the adjacent segments are displaced relative to each other about the periphery of the stent body to accommodate longitudinal flexing of the stent within the segments and without interference between adjacent segments.

8. The stent according to any one of claims 1 to 7, wherein the interconnecting elements do not bend under normal use.

9. The stent according to any one of claims 1 to 8, wherein the cylindrical segments include a first end segment having longer struts at a first end of the stent and a second end segment having longer struts at a second end of the stent, the struts of the first end segment and second end segment longer than the struts of the other segments.

10. The stent according to any one of claims 1 to 9, wherein the struts in each segment are substantially parallel to one another.

11. The stent according to any one of claims 1 to 10, wherein the orientation of the interconnecting elements reverses along the length of the stent from one segment to another.

12. The stent according to any one of claims 1 to 11, comprised of metal.

13. The stent according to claim 12, wherein the metal is a shape memory alloy.

14. The stent according to any one of claims 1 to 13 wherein the stent is thin-walled.

15. The stent according to any one of claims 1 to 14 in a self-expanding configuration.

16. The stent according to any one of claims 1 to 15 in a mechanically expandable configuration.

17. The stent according to any one of claims 1 to 16 made of Nitinol.

18. The stent, especially according to any one of claims 1 to 17, **characterized in that** adjacent segments do not bind, overlap or interfere on the inside of the bend due to a movement toward each other and into contact.

19. The stent, especially according to any one of claims 1 to 17, **characterized in that** adjacent segments do not move away from each other on the outside of the bend, leaving large gaps.

20. The stent, especially according to any one of claims 1 to 17, **characterized in that** the stent has radially and longitudinally flexibility in the stent body segments rather than in the flexible joints between the segments.

21. The stent, especially according to any one of claims 1 to 17, **characterized in that** the end segments have less compression resistance than the intermediate segments, providing a gradual transition from the native vessel to the support structure of the stent.

Fig. 1

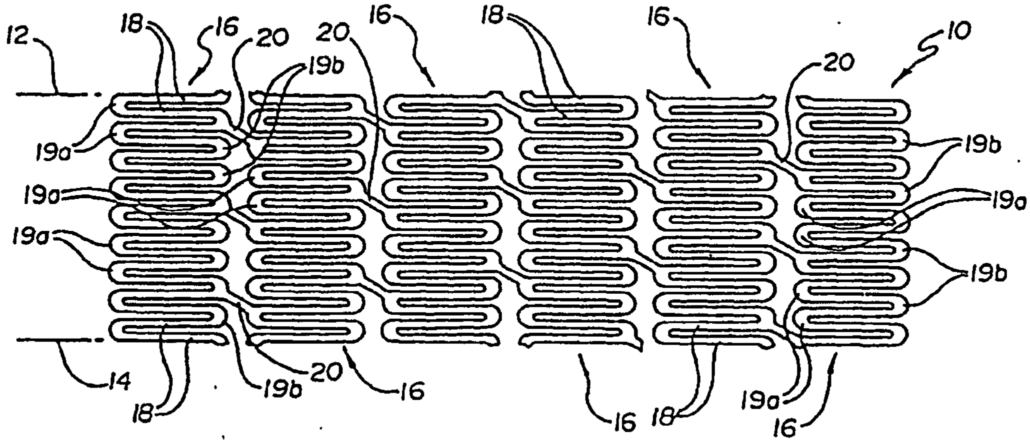
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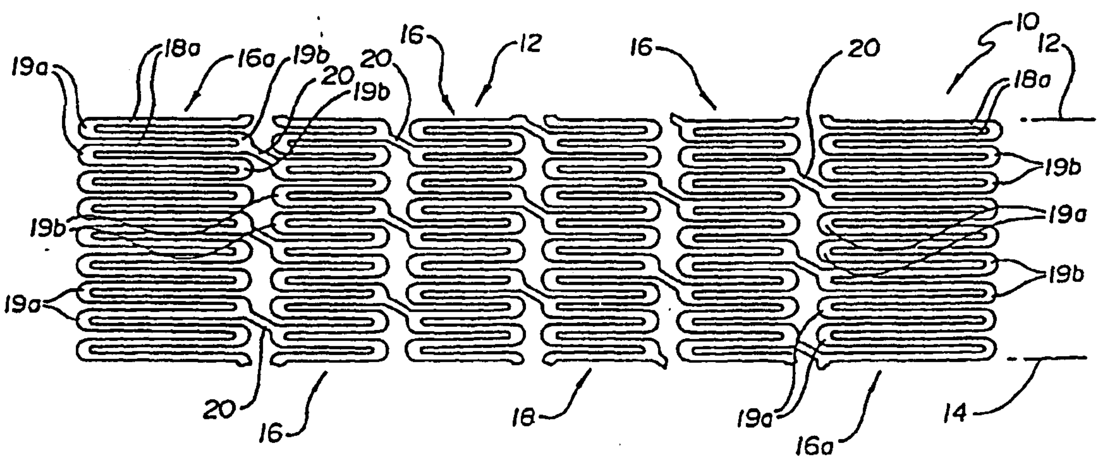
Fig. 4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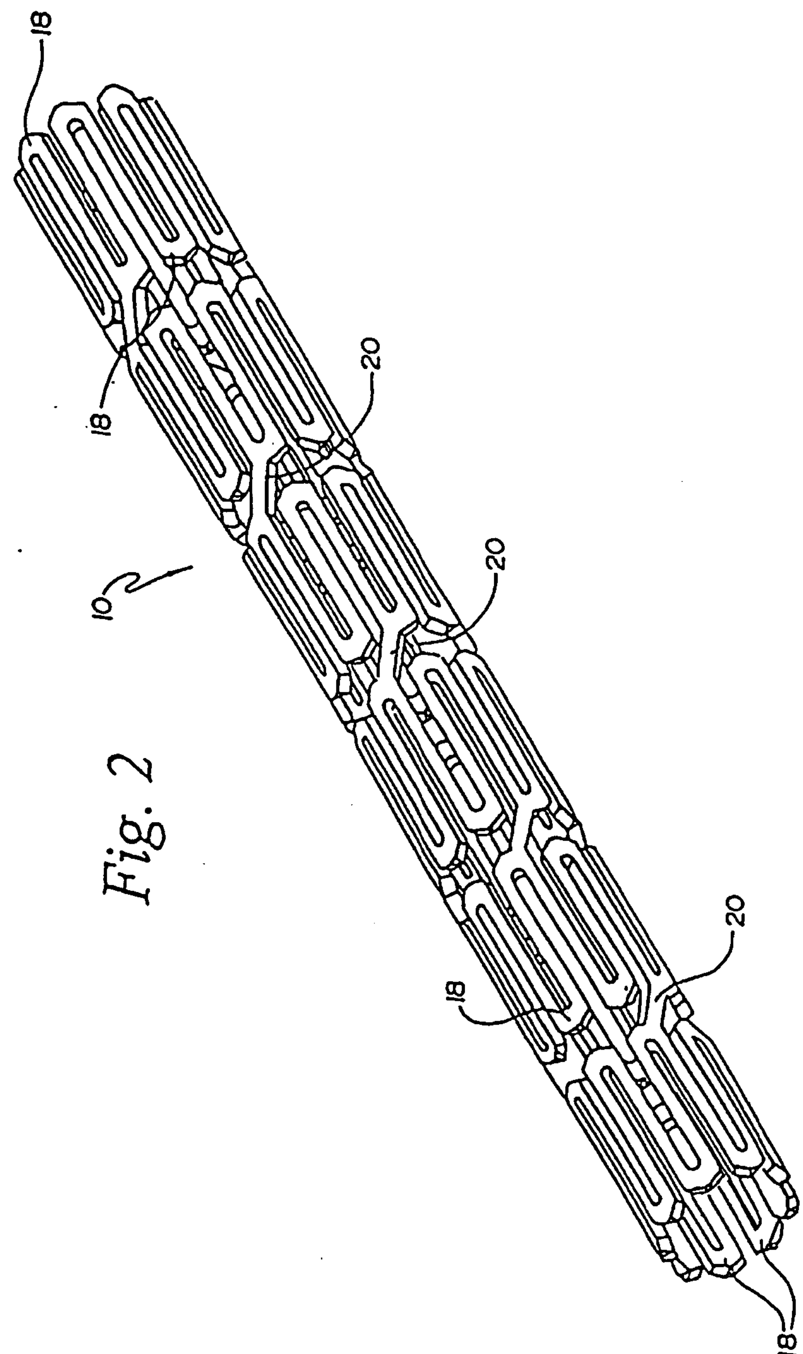

Fig. 2

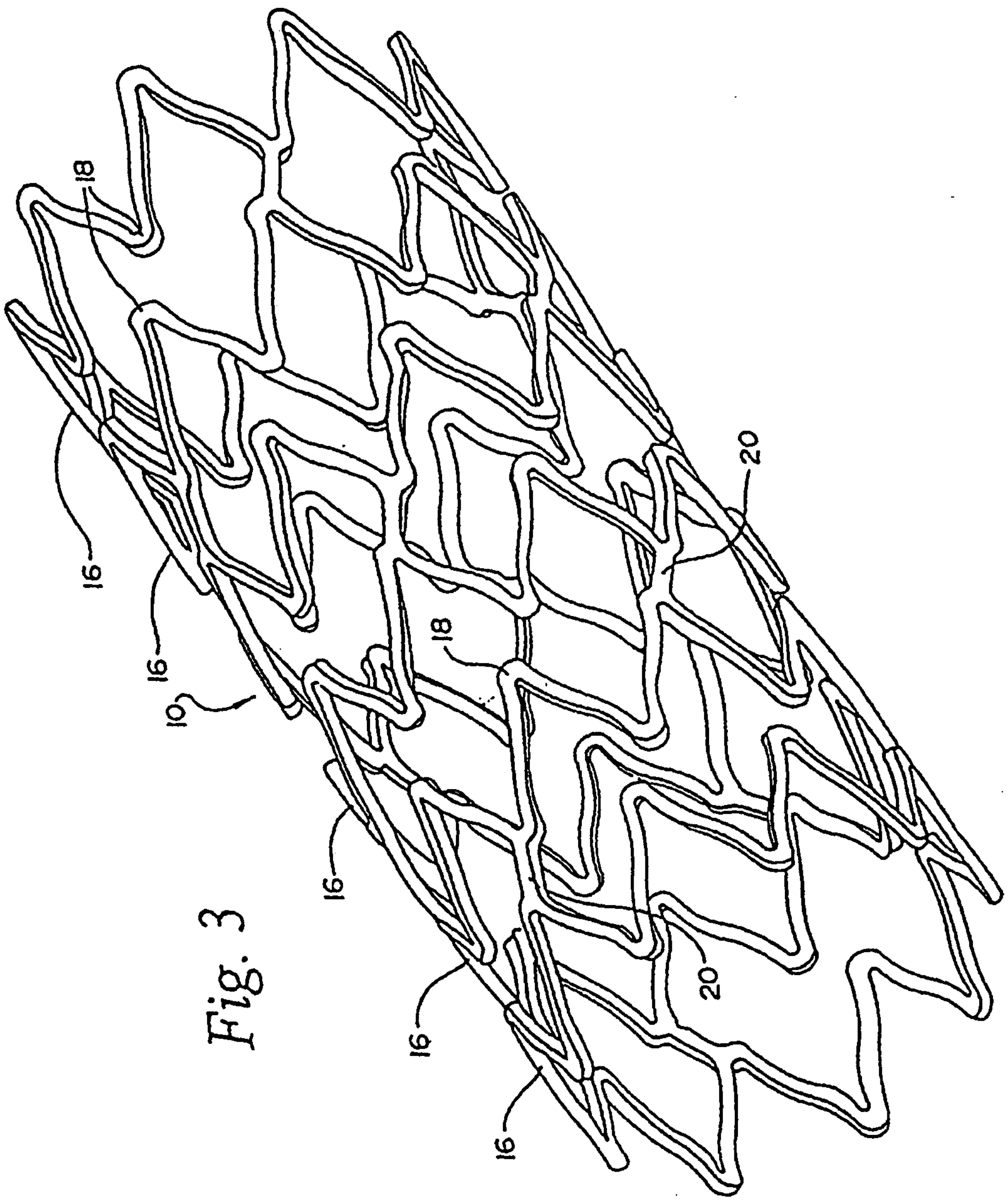

Fig. 3

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